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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,693

Applicant(s)

ROTHBARD ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 32, 33, and 40 is/are rejected.
7) ☒ Claim(s) 34-39 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S ARGUMENTS

1. The Applicant's arguments filed 6/21/05 to the rejection of claims 32, 33, and 40 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed non-persuasive for the reasons set forth below and those of record in the office action mailed 12/15/04.

Double Patenting Rejection

I. The rejection of claims 32 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 7 of US Patent No. 6,730,293 is MAINTAINED for reasons of record in the office action mailed 12/15/04.

II. The rejection of claims 32 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 106 and 116-121 of US Patent No. 6,593,292 is MAINTAINED for reasons of record in the office action mailed 12/15/04.

In each of the double patenting rejections above, Applicant asserts that no double patenting exists because the patented claims are directed to covalent bonding of the biologically active agent and transporter.

Applicant's argument is found non-persuasive because neither of the patented inventions specifically state that the biologically active agent and the transporter are covalently bound. Thus, the patented claims encompass both covalent and non-covalent bonding of the biologically active agent and the transporter.

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103 Rejection

The rejection of claims 32, 33, and 40 under 35 USC 103(a) as being unpatentable over Katz et al (US Patent No. 5,716,614) is MAINTAINED for reasons of record in the office action mailed 12/15/04 and those set forth below.

Applicant asserts that the instant invention is distinguished over Katz et al because it requires non-covalent bonding between the biologically active agent and the transporter while the bonding being the biologically active agent and the optional transporter of Katz et al is covalent.

Applicant's arguments are non-persuasive because in column 5, lines 11-65, specifically, lines 11-17 and 36-38, and 61-63, it is disclosed that the site specific complexes comprise a biologically active molecule and a residue of an omega-3 fatty acid. In addition, it is disclosed that by the term 'complex or conjugate' the interpretation is a molecule that is either held together by van der Waal's or electrostatic interaction or by covalent bonds. In lines 36-38, it is disclosed that the site specific complex may optionally comprise a poly amino acid such as polylysine, polyarginine, polyornithine, or polyasparagine. Thus, a skilled practitioner in the art would recognize that if the site specific complex involves van der Waal's, electrostatic interaction, or covalent bonding, then the addition of the poly amino may occur by non-covalent bonding. Furthermore, in column 21, lines 27-35, it is disclosed that those skilled in the art will recognize many equivalents to the specific embodiments of Katz et al's invention. In addition, the reference goes on to disclose that it is believed that non-covalent bonding may be used with Katz et al and that the concept of non-covalent

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bonding between the components is encompassed by the scope of the invention.

Hence, a skilled practitioner in the art would be motivated to non-covalently link the biologically active agent and the transporter.

CLAIM OBJECTIONS

2. Claims 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Note: The claims are allowable over the prior art of record for reasons of record.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

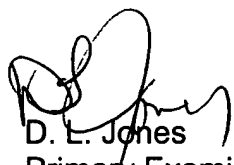
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

September 2, 2005